

11/29/10

To: ICOC

Fr: CIRM

Re: Designation of hESC lines Derived Under the Australian Research Involving Human Embryos Act as Acceptably Derived for CIRM-Funded Research

Action for ICOC Consideration:

Approval of inclusion of stem cell lines derived under license of the Australian National Health and Medical Research Council as acceptably derived, so CIRM may initiate rulemaking action under the Administrative Procedure Act.

Background:

On [11/22/10](#) the Standards Working Group (SWG) considered MES revisions to support the use of stem cell lines derived under license of the Australian National Health and Medical Research Council.

SWG Sense of the Committee:

It was the sense of the SWG that the ICOC should consider the including the lines derived under license of the Australian National Health and Medical Research Council (MRC). The following points were considered:

- ▶ The MRC rules are consistent with CIRM's acceptably derived standard.
- ▶ The two-stage informed consent process used to derived lines in Australia is exemplary.
- ▶ Certain lines derived under MRC license approach or achieve GMP-compliant standards. Such lines represent are valuable for clinical research.
- ▶ No inconsistency with established CIRM regulations exists.